GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:261
ANSWERED ON:18.02.2009
GUIDELINES ON GOOD CLINICAL LABORATORY PRACTICES
Nikhil Kumar Shri

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Indian Council of Medical Research has recently issued any guidelines on good clinical laboratory practices for laboratories engaged in medical research in the country;

(b) if so, the details thereof;

(c) whether the Government has received any complaint for such laboratories which are not providing right reports resulting in wrong treatment of patients; and

(d) the action taken/being taken by the Government in this regard?

Answer

MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) & (b): Yes, Sir. ICMR has recently prepared Guidelines on Good Clinical laboratory Practices (GCLP) for laboratories engaged in medical research as well as those catering to patient care. Generation of laboratory results is a teamwork involving patient preparation, collection of sample and its processing, analysis, reporting of results and its transmission to the researcher/treating doctor and patient. To minimize errors, laboratories should follow laid down procedures at all times. GCLP guidelines elucidate these stepwise procedures which can be adopted by laboratories engaged in research as well as patient care. The guidelines can be accessed from ICMR website www.icmr.nic.in

(c) & (d): There is no data on number of laboratories engaged in medical research which are not providing right reports resulting in wrong treatment of patients in India. However, published reports indicate the need for taking measures for detecting and preventing errors in laboratories. These include laying down rules and responsibilities and following them, conducting internal quality control procedures and external quality assurance programmes.

In India, laboratories can volunteer for accreditation of one or more services offered by them. The National Accreditation Board for Testing and Calibration Laboratories (NABL) has been providing accreditations services to medical laboratories since 1998 and is currently following ISO 15189; 2007 standards.